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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/513,086	02/24/2000	Linda S. Mansfield	MSU 4.1-458	4724

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/513,086	MANSFIELD ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/5/2003.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 4,13,45,46 and 50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4, 13, 45, 46, 50 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed February 24, 2000, claims benefit to provisional application 60/152,193, filed September 2, 1999.

Applicants amendment filed June 5, 2005, has been received and entered. Claims 1-3, 5-12, 14-44, 47-49 have been canceled. Claims 4, 13, 45, 46 and 50 have been amended. Claims 4, 13, 45, 46 and 50 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 13, 45, 46 and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants note the amendment to the claims, in particular the deletion of embodiments that include recitation of forms of the antigens/proteins encompassing recombinant and fusion proteins (pages 5-6). These amendments are noted and may be important for purposes of estoppel, however in view of the teachings of the present specification clearly these forms of antigen are contemplated. Moreover, the claims as amended recite "an" antigen, implying that there is more than one form the single naturally occurring protein. Again, consistent with the

teachings of the instant specification the present claims can reasonably be interpreted to encompass fragments, and as related to their use in the method, fragments that have the functional property of being capable of treating *S. neurona* infection in equine. The metes and bounds of the claims are being interpreted in light of the teachings of the present specification. With respect to the ability to obtain the antigens, Applicants point to example 1 where general methodology for two dimensional gel electrophoresis is set forth and argue that given this guidance one of skill in the art would be able to obtain both the 16 and 30 kDa proteins form *S. neurona* and mix them together to arrive at the composition as claimed (page 6), and that the specific amino acid sequence or a DNA sequence that encodes recombinant forms would not be needed (page 7). Examiner would agree that methods of electrophoresis and immuno-assays are well known in the art, however this is insufficient to describe relevant structural and functional elements of the claimed product, nor does it provide any guidance to the antigens nor antigenic fragments would provide a form of treatment in the claimed methodology of treating equine. As discussed above, the claims encompass more than simply naturally occurring proteins isolated from cultures of *S. neurona* by two dimensional electrophoresis. Even so, at issue is whether the specification even meets the requirements of 35 USC 112, first paragraph, for the isolated forms of the naturally occurring proteins. A search of the relevant art for disclosure of the specific sequences instantly claimed indicate that this is still a subject of research, and that new isolates provide further evidence that variants of the specific sequence are present in nature (see for example Hyun *et al.* Vet Parasitol. 2003 Feb 28;112(1-2):11-20, Sequence comparison of Sarcocystis neurona surface antigen from multiple isolates). More simply put would be an example where a specific sequence is disclosed and whether the present disclosure provides

sufficient description for the skilled artisan to recognize that the sequence was specifically contemplated as the invention. For example, Ellison *et al.* (Int J Parasitol. 2002 Feb;32(2):217-25. Molecular characterization of a major 29 kDa surface antigen of Sarcocystis neurona) teach a protein that meets the size requirements of the protein in the claimed composition, but given the present disclosure clearly the specific sequence of Ellison *et al.* would not have been predicted or even obvious given the present specification. Case law has established that one cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. Importantly, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, for the reasons above and of record it is maintained that the polypeptide sequences needed to make and use the claimed invention do meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 13 stand and newly amended claims 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Liang *et al.*

Applicants note the amendments to the claims to recite "an isolated" antigen, and thus do not read on the whole organism (page 9). Applicants' acknowledge the Examiner's summary of Liang *et al.*, however note that Liang *et al.* fails to teach isolated antigens as required by the instant claims (page 9). See Applicants' amendment, pages 8-9. Applicants' arguments have been fully considered, but not found persuasive.

Initially, it is noted that claim 45 has been amended from a method of preventing to one of treating, with an active step of administration but no specific treatment affect set forth in the claim. The amendment to the claims is noted, however the claims recite a composition 'comprising' therefore broadly encompass more than just the two antigens. At best with the term "isolated" they could be viewed as a product by process where the two antigens are isolated then recombined to form the claimed composition for use in methods of administration. In this case given the breadth of the claims, the claimed and prior art products would be considered identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the

burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Liang *et al.* teach a composition that comprises both the 16 and 30 kDa antigen of S. neurona, and methods where horses were provided this composition. Given the breadth of the instant claims, in particular to the breadth of the composition used, the teachings of Liang *et al.* anticipate the claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach